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No. 06-1249

IN THE
Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF WASHINGTON LEGAL FOUNDATION AND AMERICAN COLLEGE OF EMERGENCY PHYSICIANS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTERESTS OF *AMICI CURIAE*[1]

The Washington Legal Foundation ("WLF") is a non-profit, public-interest law and policy center based in Washington, D.C., with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending free enterprise principles, individual rights, a limited and accountable government, and the proper use of our state and federal judicial systems. To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See*, *e.g.*, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke*, 529 U.S. 89 (2000).

WLF is particularly concerned that individual freedom, the American economy, and the public health and welfare suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that frustrates the objectives or operation of specific federal regulatory regimes, such as the Federal Food, Drug, and Cosmetic Act (FDCA) at issue here.

The American College of Emergency Physicians ("ACEP") is a nonprofit, voluntary professional and educational society of over 26,000 emergency physicians

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[1] *Amici* hereby affirm that no counsel for either party authored any part of this brief, and that no person or entity other than *amici curiae* and their counsel provided financial support for the preparation and submission of this brief. All parties have consented to the filing of this brief; blanket letters of consent have been lodged with the clerk.

practicing in the United States and other countries. Founded in 1968, ACEP is the nation's oldest and largest association of emergency physicians. ACEP fosters the highest quality of emergency medical care through the education of emergency physicians, other health care professionals, and the public; the promotion of research; the development and promotion of public health and safety initiatives; and the provision of leadership in the development of health care policy.

ACEP submits this *amicus* brief on behalf of its physician members and in the interest of their patients on the basis that appropriate medical care is best determined by trained medical professionals providing care pursuant to the scope of practice afforded by their license and in compliance with federal and state regulations.

The *amici* have no direct interest, financial or otherwise, in the outcome of this case. They are filing due solely to their interest in the important issues raised by this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

At issue in this case is whether a lay jury should be allowed to impose a requirement under state tort law that conflicts with the informed judgment of the experts at the federal Food and Drug Administration that physicians should not be foreclosed from using the IV push method of injection of Phenergan as medically-indicated in their patients. The Vermont Supreme Court's decision to allow a state jury to so trump FDA's balanced determination is wrong as a matter of

preemption law under this Court's prior holdings, and it reflects a basic failure to understand the way in which such state tort law requirements can undermine federal objectives in protecting the public health.

Simply stated, in the area of prescription drugs, the argument accepted below that "more" use limitations and warnings are always "better" is fundamentally flawed. FDA's directive to Wyeth on the proper labeling of Phenergan reflected its expert determination that the benefits to the patient population as a whole of a physician option for IV push administration outweighs the adverse outcomes that might arise from human error in individual cases. The jury below could not assess that balancing question. They were not faced with the patients for whom IV push administration might be the only means for effectively receiving needed Phenergan treatment. The jury's decision, in sharp contrast to that of FDA, could not and did not take those other patients' wellbeing into account. This case highlights the reality that properly guides FDA's decision making on the labeling of prescription drugs: use limitations and warnings do not only inform, they foreclose and discourage use that provides significant health benefits. As set forth in the concrete examples discussed in Section II below, the consequences of striking the wrong balance on the side of excessive caution and overwarning can be as injurious to the public health as those on the side of underwarning.

FDA subjects prescription drugs like Phenergan to the most detailed regulatory oversight of any product available to the public, fully as rigorous as that which the Court found preemptive in *Riegel v. Medtronic, Inc.*,

128 S. Ct. 999, 1004-05 (2008). As FDA has repeatedly explained, its judgment as to the proper labeling of prescription drugs is based on a balancing of the need to inform physicians of potential adverse events against the danger of improperly dissuading beneficial drug use. In holding to the contrary that FDA requirements "merely set minimum standards," the Vermont Supreme Court below ignored the fundamental fact that prescription drugs – notwithstanding recognized potential risks – provide significant medical benefits that dramatically improve patient health. While FDA is and should be concerned that physicians have sufficient information and instruction about a drug's potential adverse effects, FDA likewise is and should be concerned that physicians are not unduly discouraged from using medically-indicated drugs for their patients.

The risk of an excessive focus on risk is not an abstract concern. The underutilization of prescription drugs in this country poses a significant public health problem, by many accounts more significant than the risks posed by the inappropriate use of potentially dangerous drugs. This underuse of beneficial medications is often driven by overwarning of alleged safety risks. There are numerous, concrete examples of overwarning that have led to serious adverse consequences to the public health, including:

(1) An increase in the teen suicide rate following new warnings of an alleged selective serotonin reuptake inhibitor ("SSRI") antidepressant drugs/suicide link that discouraged physicians from prescribing the drugs to the teenage patient population;

(2) A decrease in the IQ and other intelligence measures of babies whose pregnant mothers stopped eating fish, notwithstanding its beneficial effect on embryonic development, due to warnings of potential adverse effects of mercury contained in the fish;

(3) An increase in abortions following a "pill scare" caused by warnings in Europe of alleged increased risks of venous thrombosis arising from third generation oral contraceptives; and

(4) A resurgence of measles attributed in part to the decision by a small subset of parents to forgo vaccinations for their children because of fears of a link between the vaccines and autism.

As the expert body established by Congress to determine drug safety and labeling, FDA is charged with pursuing a balanced regulatory approach that weighs the consequences of both understating and overstating drug risks, and – as it did in determining that Phenergan should be available for use by direct intravenous injection with precisely approved warnings – FDA seeks to avoid imposing labeling requirements that would do more harm than good to the public health. A jury sitting in judgment of a single plaintiff's personal injury tort claim does not have the expertise, the information, the responsibility, or the broader public health perspective with which to make this fundamental balancing decision.

The Court's prior preemption analyses in products liability litigation has been informed largely by two fundamental questions: (1) does the federal

government specifically regulate the product safety or labeling at issue in the state tort lawsuit? and (2) does the federal government seek to balance societal costs and benefits in establishing the federal regulatory requirements at issue? Where the answer to both of these questions is yes – as it is here – the Court has consistently held that state tort claims based upon a different common law requirement are preempted.

For these reasons, WLF and ACEP respectfully request that the claim below be held preempted and that the case be remanded for entry of judgment in favor of the petitioner.

ARGUMENT

I. FDCA REQUIRES FDA TO SPECIFICALLY REGULATE DRUG LABELING BASED ON A BALANCING OF FEDERAL OBJECTIVES

A prescription drug may not lawfully be marketed in this country unless FDA makes an affirmative finding that the drug is both "safe and effective." 21 U.S.C. § 355 (2008). As the Court has explained, "[t]he determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations . . . within the peculiar expertise" of FDA. *Weinberger v. Bentex Pharms. Inc.*, 412 U.S. 645, 654 (1973). "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." *Id.* Thus, federal courts of appeals have repeatedly held that whether a drug and its labeling are safe and effective are squarely within the primary scope of FDA's

regulatory authority.[2]

FDA's requirements as to drug safety and labeling are imposed through a regulatory scheme that closely parallels the regulatory scheme for Class III medical devices that the Court found to have a preemptive effect in *Riegel*.[3] And as with Class III

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[2] *See*, *e.g.*, *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 257 (3d Cir. 2008) ("FDA is charged with promoting the public health" by, *inter alia*, "ensuring that drugs are safe and effective") (internal quotations and citation omitted); *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 170 (4th Cir. 2000) ("FDA's 'judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us.'") (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995), and *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995)); *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (same); *Rutherford v. United* States, 806 F.2d 1455, 1461 (10th Cir. 1986) ("[T]he intent behind the [FDCA] was to give the agency primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise"); *United States v. Undetermined Quantities of Various Articles of Drug Equidantin Nitrofurantion Suspension*, 675 F.2d 994, 1000 (8th Cir. 1982) ("A district court is not empowered to evaluate the actual safety and effectiveness of a drug product. That determination is committed to the FDA due to its superior access to technical expertise."); *Premo Pharm. Labs. Inc. v. United States,* 629 F.2d 795, 803 (2d Cir. 1980) (question whether a drug is safe and effective "is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue").

[3] "The substantial similarity between the premarket approval [for medical devices] and new drug application processes compels the conclusion that the latter also establishes a federal requirement with respect to labeling that can have preemptive effect." *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 794 (2002); *see also Brooks v. Howmedica*, 273 F.3d 785, 789 (8th Cir.

medical devices, FDA's determinations as to which drugs should be approved and the proper labeling of such drugs reflects "a cost-benefit analysis" in which FDA balances how many "lives will be saved" by the drug against the "risk of harm." *Riegel*, 128 S. Ct. at 1008.

The need for FDA to pursue this balanced approach was recognized by Congress in its amendment of the Food, Drug, and Cosmetic Act in 1962. As set forth in the Senate Report accompanying the 1962 Amendments, the new drug application approval procedures were designed to "strike [ ] a balance between the need for government control to assure that new drugs are not placed on the market until they have passed the relevant tests and the need to insure that government control does not become so rigid that the flow of new drugs to the market, and the incentive to undergo the expense involved in preparing them for market, become stifled." Drug Amendments of 1962, S. Rep. No. 87-1744 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 2884.

In enacting the 1997 FDA Modernization Act, Congress reaffirmed this basic principle, declaring "a clearly defined, balanced mission for the FDA" which reflects both the federal objectives of "protecting the

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2001) (noting that Class III medical devices on the market prior to enactment of the Medical Device Amendments "were deemed to have PMA approval if they had gone through the NDA approval process") (citing 21 U.S.C. § 360j(l)(3)(A)). The many detailed requirements imposed by FDA on prescription drugs are fully addressed in Petitioners' merits brief and accordingly will not be reiterated here.

public health by ensuring that the products [FDA] regulates meet the appropriate FDA regulatory standards" and of "taking appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability." Food and Drug Administration Modernization Act of 1997, S. Rep. No. 105-43 (1997), as printed in 1997 WL 394244, at *2-*4; *see also id.* at *10 (mission statement added to FDCA because "[c]lear statutory guidance is needed to assist the Agency to find this delicate balance"). Congress instructed: "the agency should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people. Approving such products can be as important as preventing the marketing of harmful or ineffective products." *Id.* at *8, *15. This balanced mission statement is set forth in FDA regulation, 21 U.S.C. §§ 393(b)(1) & (b)(2)(b) (2008),[4] and is reflected in the Court's discussion in *Buckman* of FDA's "often competing" regulatory objectives. *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348, 349-50 (2001).[5]

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[4] FDA is charged under these regulations with "promot[ing] the public health by promptly and efficiently reviewing [drug manufacturers'] clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protecting the public health by ensuring that…drugs are safe and effective." 21 U.S.C. §§ 393 (b)(1) & (b)(2)(b) (2008); *see also Colacicco*, 521 F.3d at 253.

[5] *See also* Final Rule, New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452-01, 7452 (Feb. 22, 1985) ("the final regulations [the NDA rewrite] enable FDA to act as *both a public health promoter*, by facilitating the approval of important new safe and effective therapies, and as a *public health protector*, by keeping off

Like the Department of Transportation in its regulation of automobile air bags in *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000), FDA has rejected "the more … the better" approach in achieving its federal objectives with respect to prescription drug warnings. In the preamble to its January 2006 Final Rule on prescription drug labeling, FDA explained that it seeks to achieve a balance in drug warning labels. FDA cautioned that drug labels that include overly aggressive warnings could both (1) undermine the effectiveness of other, FDA-approved warning language and (2) discourage the use of medically-appropriate drug treatments to the detriment of patient health. *See* Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

FDA first explained that more warnings can often translate into less effective warnings. "[L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to 'lose its significance.'" *Id.* at 3935. FDA noted that adopting a simplistic, "more is better" approach can lead to an overcrowding of labels that "limit physician appreciation of potentially far more significant contraindications and side effects." *Id.* The Eighth Circuit Court of Appeals has recognized the legitimacy of these FDA concerns:

> There are . . . a number of sound reasons why the FDA may prefer to limit warnings

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the market drugs not shown to meet safety and efficacy standards.") (emphasis added).

> on product labels. Warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks. A label with many varied warnings may not deliver the desired information to users.

Brooks v. Howmedica, 273 F.3d 785, 796 (8th Cir. 2001); *see Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 13 (Cal. 2004) ("Against the benefits that may be gained by a warning must be balanced the dangers of overwarning and of less meaningful warnings crowding out necessary warnings, the problems of remote risks, and the seriousness of the possible harm to the consumer."); *see also Colaccico v. Apotex, Inc.*, 521 F.3d 253, 275 (3rd Cir. 2008) (holding that FDA's assertion that "allowing unsubstantiated warnings would likely reduce the impact of valid warnings by creating an unnecessary distraction and making even valid warnings less credible" is entitled to some degree of deference).[6]

FDA next explained that excessive caution also undermines federal objectives by unduly discouraging

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[6] FDA's concern about the danger of overly-crowded warning labels was, in fact, a primary factor behind FDA's adoption of the new rule for prescription drug labeling issued in January 2006, adding a requirement that labels include a "Highlights" section up front to direct physicians to the most significant health information. In explaining its development of the new rule, FDA explained that "[i]n recent years, there has been an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to find specific information and to discern the most critical information." 71 Fed. Reg. at 3922.

physicians from using drug treatments that could help their patients. As FDA explained, the "more is better" approach "could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments." 71 Fed. Reg. at 3935. "[L]abeling that does not accurately portray a product's risks . . . [can] potentially discourag[e] safe and effective use of approved products or encourag[e] inappropriate use." *Id.* FDA cautioned:

> Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Indeed, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.

Id. In *Riegel*, the Court recognized the reasonableness of this FDA concern. *Riegel*, 128 S. Ct. at 1008, 1009 (noting that FDA applies a cost-benefit analysis that protects the interests of patients who benefit from treatment as well as those who might be exposed to potential adverse risks); *see also Colaccico*, 521 F.3d at 275 (noting FDA's view that "[u]nder-use of a drug based on dissemination of unsubstantiated warnings may deprive patients of efficacious and possibly lifesaving treatment").

FDA's explanation of its efforts to avoid the potential adverse public health consequences of a "more

is better" approach to prescription drug labeling should substantially inform the Court's analysis whether the state tort law claims here at issue conflict with or frustrate FDA regulatory determinations, regardless how the Court views the separate question of what deference is due FDA's legal position on preemption.[7] As the *Colaccico* Court recognized, "the FDA's summary of its scientific determinations must be distinguished from the agency's construction of a statute, as the review of scientific information is strictly within its expertise." 521 F.3d at 270. Moreover, "FDA's view that the imposition of liability under state law for defendant's alleged failure to warn *would* interfere with FDA's accomplishment of regulatory objectives is in our view entitled to at least as much deference, if not more, as the FDA's view of its preemption authority." *Id.* (internal quotations and citations omitted).

II. RECENT SCIENTIFIC AND MEDICAL STUDIES CONFIRM THE ADVERSE PUBLIC HEALTH CONSEQUENCES OF OVERWARNING

FDA's analysis of the potential adverse health consequences of the "more is better" approach to drug warnings is not based upon theory or abstract impressions. Medical researchers repeatedly have confirmed that the underuse of prescription drugs creates public health risks at least as significant as those of inadequate physician understanding of

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[7] *Amici* believe that FDA's preemption position is entitled to deference. This issue has been cogently addressed by FDA in its prior *amicus* brief in this case, however, and accordingly is not discussed further herein.

potential adverse drug reactions. Indeed, FDA has been confronted on numerous occasions with these real-world adverse consequences when it errs on the side of caution.

In a recent study out of the Harvard Medical School, investigators analyzed pharmacologic care in a random sample of 3,457 patients in 12 metropolitan areas in the United States and determined that "[w]hen medically indicated, appropriate medications were prescribed 62.6% of the time, suggesting significant underuse of appropriate medications." William H. Shrank, et al., *The Quality of Pharmacologic Care for Adults in the United States*, 44(10) Medical Care 936, 940 (2006). By contrast, under-appreciation of drug risks was less of a problem: physician "[p]erformance was highest in avoiding use of inappropriate, potentially harmful medications (83.5%)." *Id.* In discussing their findings, the researchers explained that "[u]nderuse of appropriate medications comprised more of the quality deficiencies than prescribing potentially harmful medications. These findings suggest that focusing solely on reducing medication errors, although a laudable goal, may miss the largest proportion of quality deficits in pharmacologic care." *Id.*; *see also id.* at 943 (discussing study results and results of earlier study of drug use in the elderly and noting "the message in both studies is the same; underuse represents a more pervasive problem than overuse of potentially hazardous drugs, and deficits exist throughout the prescribing continuum").

While there likely are a number of factors contributing to drug underutilization, medical researchers in peer-reviewed publications repeatedly

have pointed to unfounded safety concerns as a driving factor. For example, in 2005, investigators reported that "[s]everal reviews of hospital discharge data revealed that β-adrenoceptor antagonists remain significantly underutilized in patients with acute, as well as chronic coronary artery disease" and that "[m]isconceptions about the adverse effects and who would benefit probably account for physician reluctance to prescribe these medications." Michael A. Gutierrez & Arthur J. Labovitz, *Underutilization of β-Adrenoceptor Antagonists Post-Myocardial Infarction,* 5(1) Am. J. Cardiovasc. Drugs 23, abstract (2005). Another recent article discussed the barriers to effective migraine care caused by misperceptions of alleged adverse effects of prescription drug triptans. Richard Wenzel, *Migraine Headache Misconceptions: Barriers to Effective Care*, 24(5) Pharmacotherapy 638, 641 (2004) ("the vasoconstrictor effects of triptans on coronary vasculature are clinically insignificant . . . withholding of these agents from patients who may otherwise benefit, for fear of cardiac consequences, is unjustified"). And yet another article examined how misperceptions regarding alleged teratogenic risks deprive women in the United States of medically-appropriate treatment for nausea and vomiting in pregnancy. Gideon Koren & Zina Levichek, *The Teratogenicity of drugs for nausea and vomiting of pregnancy: Perceived versus real risk*, 186(5) Am. J. Obstet. Gynecol. 5248, 5252 (2002) ("in this study, we have provided evidence that because of misinformation and misperception relating to teratogenic risk, the majority of women with [nausea and vomiting of pregnancy] do not receive appropriate pharmacological or nonpharmacological treatment for this condition").

Over the past few years, FDA has been faced with a number of specific examples of how the "more is better" approach to warnings can lead to significant adverse public health consequences. While one might debate the particulars of the warnings provided in each particular case, these examples clearly illustrate the dangers of overwarning and provide a compelling explanation why FDA under FDCA establishes both a ceiling and a floor in requiring specific drug labels. Plaintiffs' conflicting "more is better" minimum standards approach can lead to serious injury to the public health.

A. SSRI Drug Warnings Lead to Increased Incidence of Suicide

Over the past twenty years, various plaintiff advocacy groups have pressed FDA to require warnings on antidepressant selective serotonin reuptake inhibitor (SSRI) drugs of a purported causal relationship with suicide and suicidal ideation. FDA repeatedly rejected the proposed warnings as scientifically unsubstantiated. In 2003 and 2004, however, a reanalysis of certain clinical trial data led FDA (and certain European regulators) to issue public health warnings about a possible association between SSRI drugs and increased suicidal thinking in pediatric patients and young adults.

Recently published research on the use of SSRI drugs and suicide rates suggest that these new warnings had a perverse effect – the incidence of suicide increased, not decreased, following their issuance. In the September 2007 issue of the *American Journal of Psychiatry*, a group of scientists supported by grants from the National Institute of Mental Health announced

the findings of a targeted study of the impacts of the SSRI warnings on suicide rates.[8] The study examined SSRI use and suicide rates following increased warnings in drug labels in the United States and the Netherlands. The findings were dramatic. In both the United States and the Netherlands, the new warnings led to significant decreases in SSRI use in pediatric patients and concomitant sharp *increases* in suicide rates in that population (reversing a long trend of decreasing suicide rates). Conversely, in patients above 60 years of age, where doctors had not been warned against SSRI drug use, the use of these medications continued to increase and the suicide rate continued to decrease. While noting that their findings were preliminary, the researchers concluded: "If the intent of the pediatric black box warning was to save lives, the warning failed, and in fact it may have had the opposite effect; more children and adolescents have committed suicide since it was introduced. If as a result of extending the black box warning to adults there is a 20% decrease in SSRI prescriptions in the general population, we predict that it will result in 3,040 more suicides (a 10% increase) in 1 year."[9]

B. Warnings Against Fish Consumption In Pregnancy Lead to Lower Child IQ Scores

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[8] Robert D. Gibbons et al., *Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 Am. J. Psychiatry 1356 (2007).

[9] *Id.* at 1361-62.

Fish and seafood are the major dietary sources of omega-3 fatty acids – especially a substance called docosahexaenoic acid – which are key nutrients for the brain and nervous system in developing fetuses, infants, and young children. Accordingly, many scientists and physicians believe that pregnant and breastfeeding women should follow a diet rich in fish and seafood. However, concerns that seafood was contaminated with mercury led FDA and EPA to issue consumer advisories in 2001 and again in 2004 warning pregnant and breastfeeding women (along with women wanting to become pregnant and young children) to eat no more than 12 ounces weekly of fish or seafood. These public advisory warnings, which were further publicized by the self-help book *What to Expect When You Are Expecting*, had an immediate impact. A study conducted in 2007 at the Medical University of South Carolina found that the warnings had caused 56% of pregnant women to cut fish consumption.[10]

In February 2007, a study published in *Lancet* found that the warnings against fish consumption in pregnancy had had the exact opposite of the intended consequence. Children of women who ate the smaller amounts of fish and seafood during pregnancy *had lower IQs and lower academic scores at age 8 and more behavioral and social problems* throughout early adolescence than youngsters whose mothers ate 12 or

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[10] *See For Pregnant Women, Benefits of Eating Ocean Fish Outweighs Concerns From Trace Levels of Mercury: Experts in Obstetrics And Nutrition Unveil Seafood Consumption Recommendations During Pregnancy*, Press release from National Healthy Mothers, Healthy Babies Coalition, *available at* http://www.brainybabieshealthykids.org/press-release-100407/.

more ounces per week.[11] On October 4, 2007, scientists with the National Healthy Mothers, Healthy Babies Coalition, a non-profit organization with 150 members including the American Academy of Pediatrics, the March of Dimes, the National Institute of Child Health and Development and the CDC, announced a sharp break from these earlier warnings, advising that pregnant and breastfeeding women should eat *at least* 12 ounces of fish and seafood per week to ensure their babies' optimal brain development.[12] The coalition scientists pointed to a growing body of evidence that selenium, a mineral that occurs in seafood at five to 20 times the concentration of mercury, may counteract potential negative influences of mercury exposure and explained that the risk of mercury toxicity is in any event quite rare as compared to the common risks of nutritional deficiency that can be counteracted by increased seafood intake.[13]

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[11] Joseph R. Hibbeln et al., *Maternal seafood consumption in pregnancy and neurodevelopmental outcomes in childhood (ALSPAC study): an observational cohort study*, 369 Lancet 578 (2007).

[12] *Seafood Recommendations During Pregnancy – October 4, 2007*, Press release from National Healthy Mothers, Healthy Babies Coalition, *available at* http://www.brainybabieshealthykids.org/seafood-recommendations-for-pregnancy.

[13] *Seafood Recommendations*, at 3 of 7.

C. Warnings Against Third Generation Oral Contraceptives Lead to Increased Rates of Abortion

On February 6, 2007, Public Citizen filed a petition with FDA seeking a ban on third generation oral contraceptives based upon an alleged increased risk of venous thrombosis as compared with second generation oral contraceptives.[14] The Public Citizen petition relied heavily on epidemiological studies conducted in the mid-1990s that have more recently been shown to be scientifically flawed and whose findings have now been rejected even by one of the original investigators.[15]

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[14] Petition to the FDA to ban third generation oral contraceptives containing desogestrel due to increased risk of venous thrombosis, available at http://www.fda.gov/ohrms/dockets/dockets/07p0044/07p-0044-cp00001-01-vol1.pdf. On July 25, 2007, FDA provided an interim response to the petition, explaining that it "has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." *See* July 25 Letter from Jane A. Axelrod to Sidney M. Wolfe, available at http://www.fda.gov/ohrms/dockets/dockets/07p0044/07p-0044-let0001-vol1.pdf.

[15] *See* Walter O. Spitzer, *The aftermath of a pill scare: regression to reassurance*, 5(6) Human Reproduction Update 736, 744 (1999) (explaining that his earlier findings of increased venous thrombosis risk were entirely due to biases and confounding factors and that "[a]n integrated balanced analysis, taking into account all the cardiovascular and cerebrovascular adverse events simultaneously, favours the view that the newer third generation OC are less risky to an unselected population of women of child-bearing age than the older OC on the market"); *see also* R.F. Kaper et al., *Third- and second-generation oral contraceptives are associated with similar risk estimates for venous thromboembolism*

Beyond having scientifically shaky foundations, Public Citizen's petition invited FDA to repeat a mistake by European regulators in the 1990s that resulted in a much publicized "pill scare" among women taking oral contraceptives. While FDA properly did not take any action following the release of the now-discredited initial studies, the British Committee on Safety of Medicines issued a "Dear Doctor" letter in 1995 warning physicians of the alleged increased venous thrombosis risk. This "Dear Doctor" letter and the wide publicity it received throughout Europe led large numbers of women in European countries to stop using oral contraceptives, resulting in an increased rate of unwanted pregnancies. As a result, three European countries, Norway, the United Kingdom, and Germany, experienced a sharp increase in abortion rates in 1996.[16] As an official from the British Public Advisory Service explained, "We recognized the ramifications of that

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5 The European Journal of Contraception and Reproductive Health Care 1,12 (2000) ("Four years after the publication of the initial four epidemiological studies on [venous thromboembolism], the weight of the evidence suggests that the risk of VTE is similar for [second and third generation] OCs.").

[16] *See* D. Osterkorn & W. Schranim, *Increase in abortions following the political 'pill scare': reaction in Germany*, 3 The European Journal of Contraception and Reproductive Health 51 (1998) (reporting a relative 15% increase in the rate of abortion in women aged 15-24 years); F.E. Skeldestad, *Increased Number of Induced Abortions in Norway After Media Coverage of Adverse Vascular Events from the Use of Third-Generation Oral Contraceptive*, 55 Contraception 11 (1997) (36% increase in abortions in women aged 15-24 years in first quarter 1996 after four years of steady declines); L. Dillner, *Pill scare linked to a rise in abortions*, 312 BMJ 996 (1996) (up to 10% increase in abortions).

announcement [of the alleged increase VT risk] straight away. … Although the government did advise women not to suddenly stop taking their pills, it seems that women did stop them abruptly because they panicked."[17]

D. Warnings Against Vaccine Lead to Outbreak of Measles

In the late 1990s, an article anecdotally linking the measles-mumps-rubella vaccine to autism resulted in a significant media outcry about the alleged dangers of the vaccine.[18] The interpretation drawing this link was subsequently retracted by most of its authors,[19] and scientific research conducted by CDC and others has now firmly established that the alleged link between the vaccine (or the preservative thimerosal used in some other vaccines) and autism/neuropsychological disorders

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[17] L. Dillner, *supra* note 16 at 996.

[18] A. J. Wakefield et al., *Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children*, 351(9103) Lancet 637 (1997).

[19] *See* Simon H. Murch et al., *Retraction of an Interpretation*, 363(9411) Lancet 750 (2004) ("We wish to make it clear that in this [earlier] paper no causal link was established between MMR vaccine and autism as the data were insufficient. However, the possibility of such a link was raised and consequent events have had major implications for public health. In view of this, we consider now is the appropriate time that we should together formally retract the interpretation placed upon these findings in the paper").

does not exist.[20] However, the public concern over warnings of an alleged health risk of vaccines has persisted.[21]

On May 1, 2008, the Centers for Disease Control announced a resurgence of measles cases during the period January 1 to April 25, 2008.[22] CDC stated that there had been 64 confirmed cases of measles reported

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[20] *See*, *e.g.*, Robert Schechter & Judith K. Grether, *Continuing Increases in Autism Reported to California's Developmental Services System*, 65(1) Arch. Gen. Psychiatry 19 (2008) (reporting increased rates of autism despite exclusion of thimerosal from vaccines); Liam Smeeth et al., *MMR vaccination and pervasive development disorders: a case-control study*, 364(9438) Lancet 963 (Sept. 11-17, 2004) (no association between MMR vaccine and autism or other pervasive development disorders).

[21] Many vaccine experts believe that the continuing misperception of an autism link was fueled by a precautionary decision by FDA to remove thimerosal from most vaccines in the late 1990s. *See* Paul A. Offit, *Thimerosal and Vaccines – A Cautionary Tale*, 357(13) NEJM 1278 (2007); *see also* Carla Williams, *Mercury-Containing Vaccine Vindicated: New Research Vindicates Thimerosal; Some Vaccine Experts [sic] Say Ban Was Premature*, ABC News (Sept. 26, 2007), *available at* http://abcnews.go.com/Health/Germs/story?id=3655803. As Dr. Paul Offit, chief of the Division of Infectious Diseases at the Children's Hospital of Pennsylvania, explained: "Although the precautionary principle assumes that there is no harm in exercising caution, the alarm caused by the removal of thimerosal from vaccines has been quite harmful." Offit, *A Cautionary Tale*, at 1279.

[22] *See* CDC Fact Sheet, *Measles – United States, January 1 – April 25, 2008*, available at http://www.wvdhhr.org/idep/pdfs/healthAlerts/talkingpoints%20for%20Measles%20Outbreak%202008.pdf.

during this period, the highest rate of infection since 2001.[23] CDC explained that "all but one of the current patients was unvaccinated or had an unknown vaccination history" and that "[t]he measles cases and outbreaks in 2008 result primarily from failure to vaccinate." *Id.* As reported by the Washington Post, CDC "[o]fficials, who have grown increasingly worried about parents shunning vaccines for their children because of safety concerns, said the measles outbreak illustrates the danger."[24] The 2008 resurgence follows closely on the heels of an outbreak of 34 measles cases in Indiana in 2005, which a CDC investigation likewise concluded was the result of parents refusing to vaccinate their children due to concerns over the alleged risk of autism.[25]

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[23] CDC noted that "[b]efore the measles vaccination program, about 3–4 million persons in the U.S. were infected each year, of whom 400–500 died, 48,000 were hospitalized, and another 1,000 developed chronic disability from measles encephalitis." *Id.*

[24] Rob Stein, *CDC Cites Largest Resurgence of Measles Since 2001*, WASHINGTON POST, May 2, 2008, at A2, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/05/01/AR2008050101806.html; *see also* Jennifer Steinhauer, *Public Health Risk Seen as Parents Reject Vaccines*, N.Y. TIMES, March 21, 2008 (quoting scientist's conclusion that "[t]he autism debate has convinced these parents to refuse vaccines to the detriment of their own children as well as the community"), *available at* http://www.nytimes.com/2008/03/21/us/21vaccine.html.

[25] Amy A. Parker, *Implications of a 2005 Measles Outbreak in Indiana for Sustained Elimination of Measles in the United States*, 355(5) NEJM 447, 452-53 (2006) ("Concern about adverse events, particularly related to media reports of a putative association between vaccinations and autism and of the dangers of thimerosal, appeared to play a major role in the decision of these

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Any contention that FDA is not and should not be concerned with the potential adverse health consequences of overwarning on drug labels ignores the real world in which FDA operates and in which patients receive – or fail to receive – appropriate medical treatment. This danger is particularly evident here. While the risk of human error with IV-push administration of Phenergan is well recognized, medical healthcare providers often conclude that the benefits of this mode of administration for particular patients outweighs the risk. In a recent survey of nearly 1,000 healthcare providers posted on the Institute for Safe Medical Practices website, only 24% of respondents agreed with the suggestion that FDA should withdraw approval for IV administration of Phenergan.[26] Indeed, "recommendations that would eliminate the use IV promethazine [Phenergan] and remove it from the formulary received the lowest scores for both perceived value and current implementation, perhaps because there are so few alternatives as effective as IV promethazine."[27]

Particularly where, as in the case of Phenergan and IV push administration, FDA has weighed the competing public health interests and required a

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families to decline vaccination.").

[26] Results of the Institute for Safe Medical Practices survey are available at http://www.ismp.org/newsletters/acutecare/articles/20061102.asp.

[27] *Id.*

balanced label that seeks to ensure the continued availability of the medical treatment at issue, juries should not be allowed to impose a different "more is better" requirement under state tort law.

III. THE COURT HAS CONSISTENTLY PREEMPTED STATE TORT LAW CLAIMS THAT WOULD IMPOSE REQUIREMENTS THAT DIFFER FROM THE BALANCED JUDGMENT OF THE FEDERAL GOVERNMENT

FDA's requirement that the Phenergan label provide physicians with the informed option to administer the drug through the IV push method is exactly the type of federal requirement that the Court has consistently found preemptive of state tort law claims. While the Court has confronted the question of preemption in products liability litigation in a variety of federal regulatory regimes involving both express and implied conflict preemption, the Court's analyses provide a consistent directive. In each case, the Court has asked two questions: (1) does the federal government regulate the specific conduct at issue in the underlying tort case, and (2) does the government's regulatory decision require a balancing of the risks and benefits of both less and more stringent government action. Where, as here, the answer to both questions is in the affirmative, the Court has recognized the conflict between state tort law and federal objectives, and the state tort claim has been held preempted.

A. The Federal Government's Regulatory Oversight of the Product Must Reach the Specific Conduct at Issue

The Court's determination whether federal law preempts a state tort law claim turns in the first instance on the extent to which the federal government regulates the specific conduct at issue. While the answer to this question may not be determinative, in each case where the Court has found specific federal oversight of the conduct allegedly violative of state tort law, it has held the state tort law claims preempted.

The importance of the scope of federal oversight to the Court's preemption analysis is apparent from a comparison of the Court's rulings in the medical device preemption cases of *Lohr* and *Riegel*. While *Lohr* and *Riegel* involved an express preemption provision in the Medical Device Amendments ("MDA") to the Federal Food, Drug, & Cosmetic Act ("FDCA"), and this case involves implied conflict preemption, the analytical issue before the Court is substantively identical. As Justice Breyer explained in his controlling concurrence in *Lohr*: "It makes sense, in the absence of any indication of a contrary congressional (or agency) intent, to read the [MDA] pre-emption statute . . . in light of these basic [implied conflict] preemption principles. The statutory terms 'different from' and 'in addition to' readily lend themselves to such a reading, for their language parallels pre-emption law's basic concerns." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 508 (1996) (Breyer, J., concurring). *See also Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 n.6 (2000) (preemption categories are not rigidly distinct); *Gade v. Nat'l Solid*

Wastes Mgmt Ass'n, 505 U.S. 88, 104 n.2 (1992) (same); *English v. General Electric Co.*, 496 U.S. 72, 79 n.5 (1990) (same).

Lohr and *Riegel* both addressed whether state tort claims involving medical devices were preempted by FDA's approval of those devices. The Court reached opposite conclusions on preemption in the two cases because of the far different nature of FDA regulation of the medical devices that allegedly caused plaintiffs' injuries. In *Lohr*, the Court held that state tort claims involving "substantially equivalent" medical devices approved under FDA's Section 510(k) process were not preempted because of the limited nature of FDA's oversight of such devices. The Court noted that FDA's review lasted "an average of only 20 hours," that FDA's decision approving the devices "focused on *equivalence*, not safety," and that the devices were "never . . . formally reviewed under the MDA for safety or efficacy." *Lohr*, 518 U.S. at 479, 493. By sharp contrast, the Court in *Riegel* held that common law tort claims involving Class III medical devices approved under the pre-market approval ("PMA") process are preempted because those devices are subject to rigorous FDA safety review: "While devices that enter the market through § 510(k) 'have never been formally reviewed under the MDA for safety or efficacy,' . . . the FDA may grant premarket approval [for a medical device] only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Riegel*, 128 S. Ct. at 1007.

The Court's other recent preemption rulings illustrate the same point. For example, in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 440 (2005), the Court

held that tort claims based on the alleged inefficacy of a pesticide were not preempted by EPA regulation of the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") because "EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause property damage." The Court made clear, however, that state tort claims were preempted to the extent inconsistent with specific EPA requirements relating to the product. *See id.* at 453 ("For example, a failure to warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted because it is inconsistent with 40 C.F.R. § 156.64 (2004), which specifically assigns these warnings to particular classes of pesticides based on their toxicity."). Likewise, in *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65-68 (2002), the Court held that state tort claims were not preempted where the Coast Guard had decided *not* to regulate whether motorboats should have propeller guards, leaving the issue open for state regulation. On the other hand, in *Geier,* 529 U.S. at 878-81, the Court held that the plaintiff's tort claims based upon the lack of airbags in an automobile manufactured by defendant were preempted because that Department of Transportation had made the affirmative regulatory decision "that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car." (internal citation omitted). And the Court held fraud-on-the-FDA claims preempted in *Buckman*, 531 U.S. 341, at 348, 349, finding that "FDA has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration"

and that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration."

B. The Federal Government's Exercise of Its Regulatory Authority Must Reflect A Balancing of Different Federal Objectives

While specific federal oversight is a condition precedent to a finding of preemption, the federal government's exercise of that authority to achieve a balance of different federal objectives generally has been conclusive. Where a state tort claim is premised on a legal standard that differs from the balance reached under federal law, the state tort claim cannot proceed.

Again, the consequence to the Court's preemption analysis of a federal regulator having balanced competing objectives is highlighted by the Court's decisions in *Lohr* and *Riegel*. In *Lohr*, the Court rejected preemption of state tort claims involving § 510(k) devices because FDA's regulation of those devices did not reflect a balancing of federal objectives: "[t]he generality of those requirements" for Section 510(k) medical devices "make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question." *Lohr*, 518 U.S. at 501. In *Riegel*, by contrast, the Court found the state tort claims preempted by FDA's balancing of federal objectives, noting that "the experts at the FDA" "apply a cost-benefit analysis," asking "How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?" *Riegel*,

128 S. Ct. at 1008.[28] The Court likewise focused on FDA's efforts "to achieve a somewhat delicate balance of statutory objectives" in finding preemption in *Buckman*. 531 U.S. at 348. As the Court explained, FDA "pursues difficult (and often competing) objectives," including ensuring that medical devices are safe and effective while also ensuring that they are "on the market within a relatively short period of time," and "regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals." *Id.* at 349, 350.

Similarly instructive are the Court's different conclusions as to the preemptive effect of the federal regulatory schemes at issue in *Sprietsma* and *Geier*. In *Sprietsma*, the Court found the Coast Guard's decision not to require propeller guards reflected "only a judgment that the available data did not meet the [Federal Boat Safety Act's] 'stringent' criteria for federal regulation" and that the Coast Guard "most definitely did not reject propeller guards as unsafe." 537 U.S. at 66-67. The Court noted that this decision presented "a sharp contrast" with DOT's decision in *Geier*, which reflected a balancing of statutory objectives. *Id.* at 67. As the Court in *Geier* explained,

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[28] *See also Riegel*, 128 S. Ct. at 1009 ("It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available – the text of the statute – suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.")

where the federal government is pursuing such a balance, the "minimum standards" argument propounded by the opponents of preemption is without merit:

> In petitioners' and the dissent's view, [the DOT regulation] sets a minimum airbag standard. As far as [the regulation] is concerned, the more airbags, and the sooner, the better. But that was not the Secretary's view. … [T]he standard deliberately provided the manufacturer with a range of choices among different passive restraint devices. Those choices would bring about a mix of different devices introduced gradually over time; and … would thereby lower costs, overcome technical safety problems, encourage technological development and win widespread consumer acceptance – all of which would promote [the regulation's] safety objectives.

Geier, 529 U.S. at 874-75.

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The Court has never allowed a state tort claim to proceed where the federal government has regulated the specific conduct at issue and established a different legal requirement based upon a balancing of federal objectives. The Vermont Supreme Court allowed exactly such a claim to proceed in this case.

CONCLUSION

The Vermont Supreme Court's holding that FDA established only minimum standards for the Phenergan label is based upon a fundamental misunderstanding of how FDA secures federal objectives in its detailed regulation of prescription drugs. FDA's rejection of a contraindication against IV push administration on the Phenergan label reflects an informed judgment that balances the federal objectives of advising physicians of potential adverse risks while not unduly discouraging physicians from using Phenergan in a manner that provides significant health benefits to patients not before a court in tort litigation. The Vermont Supreme Court's holding that a jury could reach a different conclusion under state common law without conflicting with federal law and frustrating federal objectives is in error. Plaintiff's claims are preempted, and the judgment below should be reversed.

Respectfully submitted,

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Dated: June 3, 2008